UNITED STATES DISTRICT COURT
DISTRICT OF MINNESOTA

Kimberly I. Rossum and
Randy Rossum,

Plaintiffs,

v.

Civil No. 09-3714 (JNE/LIB)
ORDER

I-Flow Corporation,

Defendant.

Yvonne M. Flaherty, Esq., and Nathan D. Prosser, Esq., Lockridge Grindal Nauen PLLP, appeared for Plaintiffs Kimberly I. Rossum and Randy Rossum.

Christian M. Ryba, Esq., Segal McCambridge Singer & Mahoney, and Benjamin A. Johnson, Esq., Johnson & Lindberg, PA, appeared for Defendant I-Flow Corporation.

Plaintiffs Kimberly I. Rossum and Randy Rossum brought this medical malpractice lawsuit against Defendant I-Flow Corporation, alleging that a pain pump manufactured by I-Flow caused permanent degeneration of cartilage in Kimberly Rossum's shoulder. Pending before the Court is I-Flow's motion to dismiss counts I-III, and VI of the Amended Complaint. *See* Fed. R. Civ. P. 12(b)(6). I-Flow argues that Plaintiffs' negligent misrepresentation and fraud counts (II and III, respectively) are preempted, and if they are not preempted, that they are not pled with sufficient particularity under Federal Rule of Civil Procedure 9. I-Flow also argues that Plaintiffs' negligence and implied warranty counts (I and VI, respectively) should be dismissed because they merge with Plaintiffs' strict liability claims. For the reasons stated below, the Court rejects I-Flow's arguments and denies its motion to dismiss.

I. BACKGROUND[1]

Defendant "designed, tested, manufactured, assembled, labeled, marketed, distributed, promoted, and sold" the On-Q PainBuster pain pump. A pain pump is a medical device that delivers a continuous dose of pain medication via catheter to a site within the body. In May 2005 Kimberly Rossum underwent shoulder surgery, which was performed by Dr. Phillip L. Prosapio. During the surgery, Dr. Prosapio installed the catheter tip of an On-Q pain pump in the joint space of Kimberly Rossum's repaired shoulder. I-Flow's representatives made representations and omissions to Dr. Prosapio regarding the safety of using the On-Q pain pump in joint spaces. Based on I-Flow's representations, Dr. Prosapio, or someone under his supervision, ordered that the On-Q pain pump be used after shoulder surgeries, including placement of the catheter in joint space. (Am. Compl. ¶¶ 25-28) Plaintiffs allege that I-Flow "misled the medical community, and the general public, by making false representations about the safety of their Pain Pump." (Am. Compl. ¶ 36) The On-Q pain pump was not safe for use in joint space, and it caused chondrolysis in Kimberly Rossum's shoulder, irreversibly destroying all or nearly all of the cartilage in it, necessitating multiple surgeries and life-long medication, and causing extreme pain and difficulty in performing basic, daily tasks.

Plaintiffs also allege that in the 1990s I-Flow attempted to obtain § 510(k)[2] approval from the Food and Drug Administration (FDA) to market I-Flow's pain pumps for use in joint space.

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[1] The facts stated below are as pled in the Amended Complaint.

[2] The 1976 Medical Device Amendments (MDA) established various levels of oversight for medical devices depending on the devices' risks.

> Class I, which includes such devices as elastic bandages and examination gloves, is subject to the lowest level of oversight: "general controls," such as labeling requirements. Class II, which includes such devices as powered wheelchairs and

The FDA denied § 510(k) approval and required I-Flow to obtain Premarket Approval (PMA) to market I-Flow's pain pumps for use in joint space. I-Flow continued to promote and design its pain pumps for use in joint space even though its request for § 510(k) approval was denied and even though it knew that the pain pumps could cause chondrolysis.

The Amended Complaint does not explicitly state whether the On-Q pain pump is a Class I, II, or III medical device. Nor does the Amended Complaint explicitly state whether the On-Q pain pump had PMA. Reading the Amended Complaint as a whole, including the paragraphs covering the attempt to obtain § 510(k) approval, however, the Court infers that there was no PMA covering the On-Q pain pump during the pertinent period. The Court also notes that it found no record of PMA for the On-Q pain pump in the FDA's online PMA database.[3] *See*

> surgical drapes, is subject in addition to "special controls" such as performance standards and postmarket surveillance measures.
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> The devices receiving the most federal oversight are those in Class III, which include replacement heart valves, implanted cerebella stimulators, and pacemaker pulse generators. . . . .
>
> Although the MDA established a rigorous regime of premarket approval for new Class III devices, it grandfathered many that were already on the market. Devices sold before the MDA's effective date may remain on the market until the FDA promulgates, after notice and comment, a regulation requiring premarket approval. A related provision seeks to limit the competitive advantage grandfathered devices receive. A new device need not undergo premarket approval if the FDA finds it is "substantially equivalent" to another device exempt from premarket approval. The agency's review of devices for substantial equivalence is known as the § 510(k) process, named after the statutory provision describing the review.

Riegel v. Medtronic, Inc., 552 U.S. 312, 316-17 (2008) (citations omitted).

[3] The Court went to http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMA/pma.cfm, entered "On-Q" in the "Trade Name" search field, and clicked the search button. The search produced no matching results. (A copy of the webpage showing the results of this search is attached to this Order as Exhibit 1.) The website does, however, indicate that the On-Q pain pump received § 510(k) clearance no later than 2007. *January 2007 510(k) Clearances*, FDA,

Mulvenon v. Greenwood, No. 10-1957, 2011 WL 2272134, at *3 (8th Cir. June 10, 2011) ("In addressing a motion to dismiss, '[t]he court may consider the pleadings themselves, materials embraced by the pleadings, exhibits attached to the pleadings, and matters of public record.'" (alteration in original) (citation omitted)). Further, during the motion hearing, Plaintiffs' counsel indicated that the On-Q pain pump was a class II device; Defendant's counsel did not object or contradict this assertion.

II. DISCUSSION

When ruling on a motion to dismiss for failure to state a claim pursuant to Rule 12(b)(6) of the Federal Rules of Civil Procedure, a court must accept the facts alleged in the complaint as true and grant all reasonable inferences in favor of the plaintiff. *Crooks v. Lynch*, 557 F.3d 846, 848 (8th Cir. 2009). Although a complaint is not required to contain detailed factual allegations, "[a] pleading that offers 'labels and conclusions' or 'a formulaic recitation of the elements of a cause of action will not do.'" *Ashcroft v. Iqbal*, 129 S. Ct. 1937, 1949 (2009) (quoting *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 555 (2007)). "To survive a motion to dismiss, a complaint must contain sufficient factual matter, accepted as true, to 'state a claim to relief that is plausible on its face.'" *Id.* (quoting *Twombly*, 550 U.S. at 570). "A claim has facial plausibility when the plaintiff pleads factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." *Id.*

A. Preemption

In its memorandum in support of its motion to dismiss, I-Flow argues that Plaintiffs' misrepresentation and fraud claims are *impliedly* preempted under *Buckman Co. v. Plaintiffs'*

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http://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/DeviceApprovalsandClearances/510kClearances/ucm083773.htm (last visited July 21, 2011). (A copy of this webpage is attached to this Order as Exhibit 2.)

Legal Committee, 531 U.S. 341 (2001). In its Reply, however, I-Flow argues that some of Plaintiffs' claims are *expressly* preempted under the MDA. *See* 21 U.S.C. § 360k(a) (2006); *Riegel*, 552 U.S. 312. Both parties addressed the express preemption issue at oral argument. The Reply is unclear as to which counts I-Flow directs its express preemption argument. In the preemption section of the Reply, I-Flow asserts that any claims based on a duty to test or failure to warn are expressly preempted. (Reply 3-5) But I-Flow has not moved for the dismissal of Plaintiffs' failure-to-warn strict-liability count and it did not argue in its opening memorandum that any claims other than the misrepresentation and fraud claims were preempted. Accordingly, I-Flow's express preemption arguments are interpreted to be directed at the negligent misrepresentation and fraud counts.

1. Implied preemption

In *Buckman*, the United States Supreme Court held that "fraud-on-the-[FDA]" claims were impliedly preempted. 531 U.S. at 353. Plaintiffs' misrepresentation and fraud claims are based on representations made to Kimberly Rossum's physician, not the FDA. Accordingly, the claims are not preempted under *Buckman*. *Lefaivre v. KV Pharm. Co.*, 636 F.3d 935, 944 (8th Cir. 2011) ("Furthermore, the present case is distinguishable from *Buckman* because Lefaivre's state-law claims are not fraud-on-the-FDA claims, as they 'focus on [harm] that is allegedly perpetrated against [consumers] rather than the FDA.'" (alteration in original) (citation omitted)).

2. Express preemption

Congress included a provision expressly preempting certain state regulations of medical devices in the MDA:

> [N]o State or political subdivision of a State may establish or continue in effect with respect to a device intended for human use any requirement—

> (1) which is different from, or in addition to, any requirement applicable under this chapter to the device, and
>
> (2) which relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device under this chapter.

21 U.S.C. § 360k(a). The Supreme Court addressed the meaning of § 360k(a) in *Riegel*, a case involving a Class III medical device that had received PMA. The Court used a two-step inquiry to determine whether a state-law cause of action is preempted under § 360k(a). First, courts "must determine whether the Federal Government has established requirements applicable" to the device. *Riegel*, 552 U.S. at 321. Second, courts "must then determine whether the [plaintiffs'] common-law claims are based upon [state] requirements with respect to the device that are 'different from, or in addition to' the federal ones, and that relate to safety and effectiveness." *Id.* at 321-22 (quoting § 360k(a)).

Regarding the first step, the *Riegel* Court held that the federal government had established requirements applicable to the device at issue because the device had PMA, which resulted in requirements on manufacturing, labeling, and marketing. A device that has received PMA must "be made with almost no deviations from the specifications in its approval application, for the reason that the FDA has determined that the approved form provides a reasonable assurance of safety and effectiveness." *Id.* at 323. Regarding the second step, the *Riegel* Court held that state common-law duties impose requirements that, notwithstanding their general nature, are "with respect to" medical devices. *Id.* at 323-30. The state common-law duties in *Riegel* were therefore preempted.

Here, there is no PMA. And, accepting all facts in the Amended Complaint as true and granting all reasonable inferences to Plaintiffs, the Court concludes that any requirements that may apply to the On-Q pain pump under FDA regulations "are not requirements *specific to the*

device in question—they reflect[] 'entirely generic concerns about device regulation generally.'" *Id.* at 322 (quoting *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 501 (1996)) (emphasis added). Accordingly, I-Flow's *Riegel* preemption argument fails on the first prong.

The device in *Lohr* had received § 510(k) approval but not PMA. Although the *Lohr* Court "disclaimed a conclusion that general federal requirements could never pre-empt, or general state duties never be pre-empted," it "held that no pre-emption occurred in the case at hand based on a careful comparison between the state and federal duties at issue." *Id.* The *Lohr* Court reasoned:

> Such a comparison mandates a conclusion that the Lohrs' common-law claims are not pre-empted by the federal labeling and manufacturing requirements. The generality of those requirements make this quite unlike a case in which the Federal Government has weighed the competing interests relevant to the particular requirement in question, reached an unambiguous conclusion about how those competing considerations should be resolved in a particular case or set of cases, and implemented that conclusion via a specific mandate on manufacturers or producers. Rather, the federal requirements reflect important but entirely generic concerns about device regulation generally, not the sort of concerns regarding a specific device or field of device regulation that the statute or regulations were designed to protect from potentially contradictory state requirements.
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> Similarly, the general state common-law requirements in this suit were not specifically developed "with respect to" medical devices. Accordingly, they are not the kinds of requirements that Congress and the FDA feared would impede the ability of federal regulators to implement and enforce specific federal requirements. The legal duty that is the predicate for the Lohrs' negligent manufacturing claim is the general duty of every manufacturer to use due care to avoid foreseeable dangers in its products. Similarly, the predicate for the failure to warn claim is the general duty to inform users and purchasers of potentially dangerous items of the risks involved in their use. These general obligations are no more a threat to federal requirements than would be a state-law duty to comply with local fire prevention regulations and zoning codes, or to use due care in the training and supervision of a work force. These state requirements therefore escape pre-emption, not because the source of the duty is a judge-made common-law rule, but rather because their generality leaves them outside the category of requirements that § 360k envisioned to be "with respect to" specific devices such as pacemakers. As a result, none of the Lohrs' claims based on allegedly defective manufacturing or labeling are pre-empted by the MDA.

Id.

This Court concludes that this reasoning applies to Plaintiffs' fraud and negligent misrepresentations claims. Further, this conclusion is supported by pre-*Riegel* and pre-*Lohr* Eighth Circuit precedent. *See Nat'l Bank of Commerce of El Dorado v. Kimberly-Clark Corp.*, 38 F.3d 988, 997 (8th Cir. 1994) ("Our conclusion . . . finds support in the numerous district court decisions that have held that preemption in the class II regulatory context is limited to the realm in which the FDA has acted."). Plaintiffs' fraud and negligent misrepresentation claims are neither impliedly nor expressly preempted.

B. Particularity under Rule 9(b)

I-Flow argues that Plaintiffs' fraud and negligent misrepresentation claims should be dismissed because they are not pled with the particularity required by Rule 9(b).

> Under Rule 9(b), a plaintiff must plead "such matters as the time, place and contents of false representations, as well as the identity of the person making the misrepresentation and what was obtained or given up thereby." In other words, the party must typically identify the "who, what, where, when, and how" of the alleged fraud. This requirement is designed to enable defendants to respond "specifically, at an early stage of the case, to potentially damaging allegations of immoral and criminal conduct." The level of particularity required depends on, inter alia, the nature of the case and the relationship between the parties. "Conclusory allegations that a defendant's conduct was fraudulent and deceptive are not sufficient to satisfy the rule." Rule 9(b) should be read "in harmony with the principles of notice pleading."

BJC Health Sys. v. Columbia Cas. Co., 478 F.3d 908, 917 (8th Cir. 2007) (citations omitted). Accepting all facts in the Amended Complaint as true and granting all reasonable inferences to Plaintiffs, Plaintiffs have alleged that I-Flow or its representatives made false representations to Kimberly Rossum's doctor regarding the safety of the On-Q pain pump for use in joint space. The representations were made before Kimberly Rossum's surgery, and her doctor relied on

them in deciding to use the On-Q pain pump in her shoulder's joint space. The On-Q pain pump then caused chondrolysis in Kimberly Rossum's shoulder.

Although there is authority supporting the dismissal of similarly pled pain-pump misrepresentation claims pursuant to Rule 9(b), *see Forslund v. Stryker Corp.*, Civil No. 09-2134 (JRT/JJK), 2010 WL 3905854, at *5 (D. Minn. Sept. 30, 2010), the Court concludes that Plaintiffs' negligent misrepresentation and fraud claims are pled with sufficient particularity. "[T]he rule regarding the pleading of fraud does not require absolute particularity or a recital of the evidence, especially when some matters are beyond the knowledge of the pleader and can only be developed through discovery." 5A Charles Alan Wright & Arthur R. Miller, *Federal Practice and Procedure* § 1298 (3d ed. 2004); *see also Abels v. Farmers Commodities Corp.*, 259 F.3d 910, 921 (8th Cir. 2001) ("Where a plaintiff is not a party to a communication, particularity in pleading may become impracticable."); *Michaels Bldg. Co. v. Ameritrust Co.*, 848 F.2d 674, 680 (6th Cir. 1988) ("Courts have held that the [Rule 9(b) particularity requirement] may be relaxed where information is only within the opposing party's knowledge. Especially in a case in which there has been no discovery, courts have been reluctant to dismiss the action where the facts underlying the claims are within the defendant's control." (citations omitted)). Here, the representations were made by I-Flow or its representatives to Kimberly Rossum's doctor; thus, the degree of particularity which otherwise might be required by Rule 9(b) is tempered because many facts concerning the representations are known only to I-Flow and Dr. Prosapio and are beyond Plaintiffs' reach without discovery. Plaintiffs' fraud and negligent misrepresentation claims pass Rule 9(b) muster. *See Strong v. Stryker Corp.*, Civil No. 10-2315 (MJD/FLN), 2010 WL 4967876, at * 3 (D. Minn. Dec. 1, 2010).

C. Merger of claims

I-Flow argues that Plaintiffs' negligence and breach of implied warranty claims should be dismissed because they merge with Plaintiffs' strict liability claims. Plaintiffs respond that consideration of merger before a factual record is before the Court is premature. I-Flow did not address this argument in its Reply. The Court accepts Plaintiffs' argument on this point. *See Bilotta v. Kelley Co.*, 346 N.W.2d 616, 622 (Minn. 1984).

III. CONCLUSION

Based on the files, records, and proceedings herein, and for the reasons stated above, IT IS ORDERED THAT:

1. I-Flow's motion to dismiss [Docket No. 77] is DENIED.

Dated: July 31, 2011

s/ Joan N. Ericksen
JOAN N. ERICKSEN
United States District Judge